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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/623,726	09/07/2000	Christer Alstermark	3525-94	6282

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10/21/2002

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EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 10/21/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/623,726

Applicant(s)
ALSTERMARK et al.

Examiner
Brenda Coleman

Art Unit
1624



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 9, 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 24-39 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 24-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 10 & 12 6) ☐ Other:

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DETAILED ACTION

Claims 1-18 and 24-39 are pending in the application.

This action is in response to applicants' amendment dated July 9, 2002. Claims 1, 16, 26 and 33 have been amended and claims 38 and 39 are newly added.

Response to Arguments

Applicants' arguments filed July 9, 2002 have been fully considered with the following effect:

1. The applicants' amendments and arguments are sufficient to overcome the 35 U.S.C. § 112 second paragraph rejections labeled a)-h). However, with regards to the 35 U.S.C. § 112 second paragraph rejection labeled i) of the last office action, the applicants' amendments and remarks have been fully considered but they are not persuasive. The following reasons apply:

- i) The applicants' stated that "protected derivative would be completely clear to one of ordinary skill in this art" and that "one of ordinary skill would appreciate that a protective group has to serve the function of preventing, under certain conditions, reactions of the functional group that it is intended to protect". However, it is the applicant's specification for which the ordinary practitioner need to turn to for guidance as to what is meant by "protected derivative". It is recognized that a protecting group is often used in a process, however, it is the compounds which are being claimed and "protected derivative" does not define the compounds which the applicants are seeking patent protection for. The applicant's specification does

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not sufficiently define the applicants metes and bounds of the compounds as claimed herein.

Claims 26-34 and new claim 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For reasons of record and stated above.

2. The applicants' amendments and arguments are sufficient to overcome the 35 U.S.C. § 101 rejection of the last office action, which is hereby **withdrawn**.

3. The applicants' amendments and arguments are sufficient to overcome the 35 U.S.C. § 102 anticipation rejections of the last office action, which are hereby **withdrawn**.

4. The applicants' amendments and arguments are sufficient to overcome the 35 U.S.C. § 103, obviousness rejections of the last office action, which are hereby **withdrawn**.

5. The applicants' amendments and arguments are sufficient to overcome the obviousness-type double patenting rejection of the last office action, which is hereby **withdrawn**.

In view of the amendment dated July 9, 2002, the following new grounds of rejection apply:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-18, 24 and 39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The scope of “pharmaceutically acceptable protected derivative” is not adequately enabled. The applicants pointed to page 38 which states that “protected derivatives of compounds of formula I” may be described as “prodrugs”. Applicants provide no guidance as how the compounds are made more active *in vivo*. The choice of a “prodrug” will vary from drug to drug. Therefore, more than minimal routine experimentation would be required to determine which prodrug will be suitable for the instant invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-18, 24, 33 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a) Claims 1-5, 7-18, 24 and 39 are vague and indefinite in that it is not known what is meant by C₄ alkyl in the definition of R⁹.

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- b) Claims 1-11, 15-18, 24 and 39 are vague and indefinite in that it is not known what is meant by the proviso labeled (c)(ii) where B represents $-(CH_2)_nN(O)_p-$.
- c) Claim 15 recites the limitation " $=O$ " in the definition of the substituents on the phenyl ring. There is insufficient antecedent basis for this limitation in the claim.
- d) Claim 33 is vague and indefinite in that it is not known what is meant by the variable R^{44} which is not defined in the claim.
- e) Claim 33 recites the limitation " R'' " in the definition of the variables of formula XXIII. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-15, 17, 18, 24, 25, 35-37 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lubisch et al., U.S. Patent No. 4,959,373. The generic structure of U.S. '373 encompasses the instantly claimed compounds (see Formula I, column 2) and for the same uses as claimed herein. The examples differ only in the nature of the R , R^1 , R^3 , Y , R^2 , X and Z substituents. Column 1, line 59 through column 2 line 26 defines the substituent R , R^1 and R^3 are identical or different and are each H , C_1 - C_4 -alkyl, halogen or C_1 - C_4 -alkoxy; when Y is $-C(=O)-$

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NH- then R² is C₁-C₄-alkyl, halogen, -CN, C₁-C₄-alkoxy, -NHSO₂CH₃, -CF₃, NH-acetyl or NR⁹R¹⁰; X is -CH₂-, -C(O)- or -C(R⁶)(OR⁷)- and Z is C₁-C₄-alkylene. Compounds of the instant invention are generically embraced by U.S. '373 in view of the interchange ability of the R, R¹, R³, Y, R², X and Z substituents of the bispidine ring system. Thus, one of ordinary skill in the art at the time the invention was made would have been motivated to select for example Y is -C(=O)-NH- as well as other possibilities from the generically disclosed alternatives of the reference and in so doing obtain the instant compounds in view of the equivalency teachings outlined above.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 33 and 35-37 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 20, 25, 27 and 28 of U.S. Patent No. 6,294,475. Although the conflicting claims are not identical, they are not patentably distinct from

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each other because the compounds of formula XXIII are embraced by the claims of U.S. '475 where R⁷ is an optionally substituted phenyl.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is (703) 305-1880. The examiner can normally be reached on Mondays from 8:30 AM to 5:00 PM, on Tuesdays from 8:00 AM to 4:30 PM, on Wednesday thru Friday from 9:00 AM to 5:30 PM.

The fax phone number for this Group is (703) 308-4734 for "unofficial" purposes and the actual number for **OFFICIAL** business is **308-4556**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.



Brenda Coleman
Primary Examiner AU 1624
October 18, 2002